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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,077	10/29/2003	Cynthia B. Robinson	02486.0067.NPUS01	9188

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EXAMINER

RAMACHANDRAN, UMAMAHESWARI

ART UNIT PAPER NUMBER

1617

MAIL DATE DELIVERY MODE

07/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/698,077

Applicant(s)

ROBINSON ET AL.

Examiner

Umamaheswari Ramachandran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicants' election of group I, claims 1-14 without traverse in the reply filed on 3/6/2007 is acknowledged. Applicants' have elected the following species with traverse (received in the office on 5/4/2007). 1) non-glucocorticoid steroids--- dehydroepiandrosterone-sulfate (DHEA-S) 2) PDE-4 inhibitors----cilomilast 3) Ubiquinones--formula (II) claim 6, n=1 0. Claims 1-14 are pending.

### ***Response to Remarks***

Applicants' have argued that non-elected species would not require a burdensome search. In response, the instant application contains claims are directed to the following patentably distinct species: the species of non-glucocorticoid steroids; the species of PDE-4 inhibitors; the species of ubiquinones; The species of non-glucocorticoid steroids, PDE-4 inhibitors, and ubiquinones are independent or distinct because they are different chemical compounds with different structures, chemical and physical properties, bioavailabilities, pharmacokinetic profiles, and pharmacological efficacy. Because the species have different structures and properties, different searches are required for each species, which presents a substantial burden to the Office. The restriction requirement is made final.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/923,387. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the pending application teach a pharmaceutical composition comprising the first active agent which is one of non-glucocorticoid steroid and a second active agent which is PDE-4 inhibitor. The instant application teaches non-glucocorticoid steroid species encompassed by the genus non-glucocorticoid steroid compounds taught by the co-pending application. The claims (1-14) of the instant application fall within the scope of the claims 1-15 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyce (2002/0032160) in view of Meade et al. (US 2005/0026886, effective filing date, Jul 29 2003).

Nyce teach a composition and various formulations comprising therapeutic amounts of non-glucocorticoid steroid of formula I (para 0018) wherein R1 of formula I is hydrogen or SO<sub>2</sub>OM, wherein M comprises H, Na, sulfatide etc (para 0019). The reference further teaches that the composition includes the compounds of formula I such as DHEA, analogue thereof or salt thereof such as dihydroepidandrosterone sulfate, and/or a ubiquinone of formula II (elected species) or salt thereof, and a pharmaceutically or veterinarily acceptable carrier or diluent that are useful for treating bronchoconstriction, respiratory tract inflammation, allergies, asthma etc (see Abstract, para 0023, p 7, claim 1, p 8, claims 2-7, 11 and 14, p 9, claim 52). The reference further teaches that the compositions can be administered by generating an aerosol or spray comprised of respirable, inhalable, nasal or intrapulmonary delivered particles ranging from 10 to about 100 u in size (p 8, claims 35, 37, 39). The reference further teaches a kit comprising such formulation and a delivery device, comprising an inhaler wherein the formulation comprises an inhalable, respirable, intrapulmonary or nasal formulation and the inhaler comprises a nebulizer or insufflator and delivers individual premeasured doses of the formulation (p 9, claims 42, 43-47).

The reference does not teach a second agent PDE-4 inhibitor in the composition.

Meade et al. teach a pharmaceutical composition comprising a PDE IV inhibitor such as cilomilast and their use in the treatment of respiratory disorders that include

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asthma and chronic obstructive pulmonary disorder (see Abstract, p 3, para 0026, p 12, claims , 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add cilomilast in a composition comprising DHEA and ubiquinone. The motivation to do so is provided by Meade et al. Meade et al. teach a pharmaceutical composition comprising a PDE IV inhibitor such as cilomilast and further teaches that the composition is useful in the treatment of respiratory complaints. One of ordinary skill in the art would have been motivated to add a PDE-4 inhibitor such as cilomilast to a composition comprising DHEA and ubiquinone as both the compositions have been shown to be useful in the treatment of asthma and one can expect similar success and further expect additive or synergistic effects in the combination therapy. The examiner respectfully points out the following from MPEP 2144.06: "It is **prima facie obvious** to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their, having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069,-1072 (CCPA 1980).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyce (2002/0032160) in view of Compton et al. (The Lancet, 358, July 28, 2001).

Nyce teachings discussed as above.

The reference does not teach a second agent PDE-4 inhibitor in the composition.

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Compton et al. teach cilomilast is orally active, potent and selective inhibitor of phosphodiesterase 4 and potential therapeutic actions include bronchodilation (p 266, col. 1, lines 4-13). The reference further teaches the safety, efficacy and dose response of cilomilast in a method of treatment of chronic obstructive pulmonary disease (COPD) (see Abstract, see Results, figures 2-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add cilomilast in a composition comprising DHEA and ubiquinone. The motivation to do so is provided by Compton et al. Compton et al. teach an oral formulation of cilomilast in a method of treatment of COPD. One of ordinary skill in the art would have been motivated to add a PDE-4 inhibitor such as cilomilast to a composition comprising DHEA and ubiquinone as both the compositions have been shown to be useful in the treatment of respiratory disorders and one can expect similar success and additive or synergistic effects in the combination therapy. The examiner respectfully points out the following from MPEP 2144.06: "It is **prima facie obvious** to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their, having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069,-1072 (CCPA 1980).

### **Conclusion**

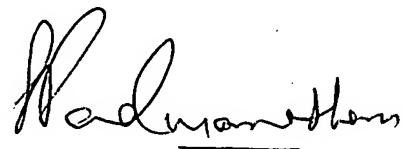
No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER